REMARKS

Claims 1-35 are pending. Claims 1, 2, 4, 7, 8 and 11 are under examination, with claims 3, 5, 6, 9, 10 and 12-35 being withdrawn. Claims 1, 4, 11 and withdrawn claim 30 have been amended. Claim 7 has been canceled.

Claim amendments

Claims 1 and 30 (withdrawn) have been amended with the addition of the phrase "and a linker capable of self-immolation linking the biologically active compound and the transport moiety". This is not new matter. The subject of this amendment is addressed at page 14, line 21 through page 18, line 25. These pages provide extensive descriptions of self-immolating linkers, including four formulae that are included in the claims.

Rejection of Claims 1, 2, 7 and 8 Under 35 USC § 102(b)

The examiner has rejected claims 1, 2, 7 and 8 as anticipated by the publication Lorenzen et al., The Journal of Cell Biology, 1995, 131:631-643 ("Lorenzen"). The examiner states that the size of the protein in Lorenzen is irrelevant because the instant claim 1 recites a transport moiety "comprising" a specified sequence, allowing additional protein or other substance to be present beyond the specified linker sequence. The examiner concludes that because the Lorenzen sequence RKRKR reads on the structures of instant claims 1 and 2, it inherently has the desired property of being a transport moiety.

Applicants note these rejections, and point out that claim 1 has been amended, creating another distinction between the Lorenzen molecule and the molecules of the instant claims. In particular, the phrase "and a linker capable of self-immolation linking the biologically active compound and the transport moiety" has been added to claim 1, thereby adding an element to the claims that is not described or implied in Lorenzen.

Lorenzen teaches a peptide as part of a test peptide encoding a detectable marker protein and an amino acid sequence that includes TCPCP. The test peptide localizes to the nuclear membrane of a cell, where the marker is transcribed and translated in the cytoplasm. By deletion analysis, Lorenzen claims that a downstream RKRKR sequence localizes the peptide to the nuclear membrane. However, this does not anticipate instant claims 1 or 2. In the instant claims, there are three separate regions that are covalently joined together: (1) the biologically active

compound, that is (2) linked by a linker, to (3) the transport region. Not only is there is no linker between the region that can optionally be RKRKR and the expressed marker region of the Lorenzen test peptide, there is no non-amino acid, self immolating linking moiety.

The currently claimed invention provides the user the benefit of taking three separate elements, as noted above, and bringing them together to create a conjugate that can increase the amount of biologically active compound that can pass through a biological membrane, such as a cellular membrane. After passage of the conjugate through a biological membrane, the linker self-immolates, leaving a peptidyl transporter and the desired biologically active compound.

Because anticipation requires the presence of all elements in the anticipating art, Lorenzen does not anticipate claims 1, 2 or 8, claim 7 being canceled after incorporation into claim 1.

Rejection of Claims 1 and 4 Under 35 USC § 102(b)

The Examiner has rejected claims 1 and 4 as anticipated by Olsson et al., Biochim. Biophys. Acta, 1991, 1097:37-44 ("Olsson"). Applicants traverse this rejection. While Olsson teaches a sequence that reads on the transporter sequence of the present claims—$(ZY)_mZ$ where Z is arginine and S is an amino acid that does not comprise an amidino or guanidino group (serine in this case), Olsson does not teach all of the elements of the instant claims. Olsson lacks a teaching of a covalently bound linker between the transport moiety and a biologically active compound, let alone a teaching of a self-imollating linker. In fact, the arginine-serine region taught by Olsson is not bound at all to the biologically active compound. Instead, it is used in a competition binding assay.

Because anticipation requires the presence of all elements in the anticipating art, Olsson does not anticipate claims 1 and 4.

Rejection of Claims 1, 2, 4, 7 and 8 Under 35 USC § 102(e)

The Examiner has rejected claims 1, 2, 4, 7 and 8 as anticipated by Mixson, US Patent 7,070,807. Applicants traverse this rejection. Claim 7 has been canceled. As with the other references described above, Mixson does not teach a self-immolating linker. Mixson discloses a composition of a transport polymer and "at least one pharmaceutical agent in association with the transport polymer". Mixson does not teach a linker, let alone a self-immolating linker, between

the pharmaceutical agent and the transport polymer. Instead, Mixson refers to associations such as a liposome, dendrimer, virus or virosome used as an intracellular delivery component "in association" with the transport molecule. While Mixson, at column 15, lines 30-44, refers to possible covalent connections between the pharmaceutical agent and the transport molecule, no mention of a self-immolating linker between the agent and the transport.

Because anticipation requires the presence of all elements in the anticipating art, Mixson does not anticipate claims 1, 2, 4 or 8.

Rejection of Claims 1, 2, 4, 7, 8 and 11 Under 35 USC § 112, First Paragraph

The Examiner has rejected all of the pending claims as not meeting the description requirement due to the presence of $(ZY)_mZ$ where m is an integer from 3-10. Applicants have removed this text. Therefore, applicants believe that the claims as currently amended meet the description requirement of § 112, first paragraph.

CONCLUSION

Applicants believe the currently examined claims are now in form for allowance. Because the generic claim 1 is now allowable, applicants respectfully request that the examiner consider the non-elected species. Applicants also request that the linking claims be allowed, and that the method claims, which have been amended along with the pending claims, be rejoined and allowed.

Respectfully submitted,

By:

Carol A. Schneider, Ph.D., J.D.
Registration No. 34,923
c/o Mintz Levin
1400 Page Mill Road
Palo Alto, CA 94304
(650) 251-7702

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